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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/756,649	01/03/2001	Eugene de Juan JR.	55535 (1699)	1507

21874 7590 02/25/2003

EDWARDS & ANGELL, LLP
P.O. BOX 9169
BOSTON, MA 02209

EXAMINER

JEFFERY, JOHN A

ART UNIT	PAPER NUMBER
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3742

DATE MAILED: 02/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.



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7590 12/04/2002

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EXAMINER

JEFFERY, JOHN A

ART UNIT PAPER NUMBER

3742

DATE MAILED: 12/04/2002

remail

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Office Action Summary

Application No.

09/756,649

Applicant(s)

DE JUAN ET AL.

Examiner

John A. Jeffery

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 October 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 61-107 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 61-107 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 21 October 2002 is: a) ☒ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Translation of SU733670

DETAILED ACTION

Pending Claims

The examiner acknowledges Applicant's statement on Page 10 of the amendment filed 10/21/02 that "[c]laims 1-60 are pending." However, the examiner notes for the record that because claims 1-60 were cancelled, they are technically no longer pending; rather, newly-added claims 61-107 are currently pending.

Claim Objections

Claims 88, 89, 95, 96, and 99-106 are objected to because of the following informalities:

Claim 88: A hyphen must be inserted between "self" and "contained."

Claim 89: The term "can be" must be changed to "is adapted to be" for more positive recitation.

Claim 95: In line 2, "place" must be changed to "placed."

Claim 99: In line 1, "bring" must be changed to "bringing."

Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 62, 63, 85, and 93 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 62 and 93: In line 2, no antecedent basis exists for "the environment."

Claim 63: In line 2, the term "preferably" does not positively recite the limitation that follows and therefore introduces an ambiguity in the claim rendering the claim indefinite. It is not clear whether the limitation that follows "preferably" is a required feature of the claim or is merely precatory. See, e.g., *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989) (noting that broad language followed by narrow language can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (1) merely exemplary of the remainder of the claim, and therefore not required, or (2) a required feature of the claims). See also *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). For purposes of examination, the examiner presumes that "preferably" was intended to refer only to the amplification of the "information" and that particular feature is therefore optional. However, the examiner presumes the "communication" limitation that follows is a required feature of the claim.

Claim 85: In line 2, no antecedent basis exists for "the shaft."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this action:

A person shall be entitled to a patent unless -

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 61-68, 70-74, 76, 79, 80, 85, 88, 89, 94, 97, 99-101, and 103-106 are rejected under 35 USC 102(b) as being anticipated by SU733670. SU733670 discloses a surgical instrument for use in cornea removal surgery comprising a strain gauge that detects changes in pressure from the underlying tissue during use. The detected pressure from the strain gauge is used as a control signal to change the audible tone or sound volume thereby providing audible feedback to the surgeon during use.

According to the English language translation of SU '670 (see attached), changes in the pressure exerted by the blade on the tissue is dynamically indicated by an associated proportional change in tone of the sound. Therefore, by monitoring such changes in pitch while cutting, the physician obtains real-time information regarding the changes in (1) tissue density, (2) tissue resistance, and (3) depth of the cut. With regard to claim 80, while a power source is not expressly stated in the reference text, a power source is implicit in the disclosure because the instrument involves taking an electrical transducer signal, amplifying it, and subsequently transforming the amplified signal to an acoustic signal. Such electrical processes necessarily require a source of electrical power.

Joint Inventors--Common Ownership Presumed

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligations under

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37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 75, 81-84, 90-92, and 98 are rejected under 35 U.S.C. 103(a) as being unpatentable over SU733670 in view of EP349443. The claims differ from the previously cited prior art in calling for a piezopolymer element to generate an electric signal proportional to the degree of flexion. While SU '670 discloses a rigid surgical instrument, the use of surgical cutting instruments with flexible tips is conventional and well known in the art as evidenced by EP349443 noting the flexible tip which also includes a sensor which detects the degree of flexion of the tip so that the forces exerted on the tip are measured and the incision is guided more accurately. See Abstract, particularly the "USE/ADVANTAGE" section. Also, a flexible tip would enable the instrument to be introduced in difficult-to-reach areas internally. In view of

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EP349443, it would have been obvious to one of ordinary skill in the art to provide a flexible tip with flexion detection means in conjunction with the previously described apparatus so that an instrument was provided that could reach difficult-to-reach internal areas via a flexible tip yet still provide a measure of the forces applied to the flexible tip during cutting. With regard to claim 75, while SU '670 does not expressly state the means for producing the audible signal, the examiner takes Official Notice that the use of electro-acoustic devices to generate sound from an electrical signal such as speakers, earphones, and the like are well known in the art and does not constitute a patentably distinguishable feature of the invention. With regard to claims 81 and 82, the use of battery power sources is conventional and well known in the art in view of a battery's ability to provide a self-contained power source precluding the need to access mains power. The use of a connecting cable is conventional and well known in the art in order to provide an insulated power source electrical connection to improve safety and facilitate prompt and easy replacement of the power source. With regard to claims 90-92 and 98, the use of modular, disposable, and reusable surgical instrument tips is well known in the art so that replacement tips can be easily installed on the device as well as having the ability to reuse a replaced tip thereby lowering costs and reducing waste.

Claims 69 and 102 are rejected under 35 U.S.C. 103(a) as being unpatentable over SU733670 in view of the article by Tanimoto et al entitled "Micro Force Sensor for Intravascular Neurosurgery and *In Vivo* Experiment" ("the Tanimoto article"). The

claims differ from the previously cited prior art in calling for the device to be used in neurosurgical applications. The use of devices with force-sensing capability in neurosurgical applications is conventional and well known in the art as evidenced by the Tanimoto article which teaches using a micro-force sensor for surgical tools in neurological applications so that the delicate neurological regions are detected during surgery thereby minimizing damage and obtaining information about certain neurological disorders such as aneurysms. In view of the Tanimoto article, it would have been obvious to one of ordinary skill in the art to use a force-sensing tool of the previously described apparatus for neurosurgical applications so that the delicate neurological regions are detected during surgery thereby minimizing damage and obtaining information about certain neurological disorders such as aneurysms.

Claims 77, 86, and 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over SU733670 in view of Brown et al (US4841987). The claims differ from the previously cited prior art in calling for a microprocessor with the ability to adjust sensitivity and threshold of operation. Providing a microprocessor to process the electrical input from a force sensor in a surgical tool is conventional and well known in the art as evidenced by Brown et al (US4841987) noting microprocessors 309, 325, and 321 in Fig. 3. Moreover, potentiometers 306, 310 enable sensitivity adjustment. In view of Brown et al (US4841987), it would have been obvious to one of ordinary skill in the art to provide a microprocessor in conjunction with the previously described apparatus so that an integrated processing means was provided with low power consumption and

light weight thereby reducing the number of apparatus parts and drain on the power source.

Claims 95 and 96 are rejected under 35 U.S.C. 103(a) as being unpatentable over SU733670 in view of Hall (US5411511). The claims differ from the previously cited prior art in calling for the device to comprise a shaft and a handle wherein the sensor is placed between the shaft and the handle. Providing a force sensor between a shaft and a handle on a surgical cutting apparatus for eye surgery is conventional and well known in the art as evidenced by Hall (US5411511) noting Figs. 7 and 8 wherein sensor 30 is placed between shaft (lower portion of 25 in Fig. 7) and the "handle" 35. According to col. 6, lines 4-25, by mounting the sensor in this fashion, the amount of pressure applied to the knife by the surgeon's fingers proportional to the resistance the cornea exerts on the blade is accurately detected. In view of Hall (US5411511), it would have been obvious to one of ordinary skill in the art to so mount the sensor of the previously described apparatus so that the amount of pressure applied to the knife by the surgeon's fingers proportional to the resistance the cornea exerts on the blade is accurately detected.

Claim 93 is rejected under 35 U.S.C. 103(a) as being unpatentable over SU733670 in view of Shan (US5728044). The claims differ from the previously cited prior art in calling for sensing impedance or flux. However, providing strain gages to sense a change in electrical impedance responsive to flexion of a surgical tool is

conventional and well known in the art as evidenced by Shan (US5728044) noting col. 6, lines 27-35 where an array of strain gages senses a change in electrical impedance to determine the degree of bending of a surgical tool. In view of Shan (US5728044), it would have been obvious to one of ordinary skill in the art to sense impedance in conjunction with the previously described apparatus so that an electrical parameter was used as the force sensing control signal thereby facilitating straightforward processing of the signal via microprocessors and other computing equipment.

Claim 77 is rejected under 35 U.S.C. 103(a) as being unpatentable over SU733670 in view of Aristides (US5928158). The claim differs from the previously cited prior art in calling for the transducer to be attached to a grip portion of the device. Attaching speakers to the grips of surgical tools is conventional and well known in the art as evidenced by Aristides (US5928158) noting speaker 15A in Fig. 1A which emits a sound warning the surgeon when nerves are contacted. Disposing the speaker in the grip housing precludes the need to have a separate speaker housing thus reducing the number of apparatus parts. In view of Aristides (US5928158), it would have been obvious to one of ordinary skill in the art to dispose the speaker of the previously described apparatus in the grip thereby precluding the need to have a separate speaker housing thus reducing the number of apparatus parts.

Claim 78 is rejected under 35 U.S.C. 103(a) as being unpatentable over SU733670 in view of Epstein (US5437657). The claim differs from the previously cited

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prior art in calling for the transducer to be attached to the medical practitioner using the device. Providing an electromechanical transducer attached to the surgeon so that audible signals are directed solely to the practitioner is conventional and well known in the art as evidenced by Epstein (US5437657) noting headphones 250 which are worn by the surgeon while using the surgical instrument during eye surgery so that an audible warning is heard by the surgeon when the correct depth is achieved. The use of headphones ensures that the surgeon can hear the warning by blocking out ambient and background noise. In view of Epstein (US5437657), it would have been obvious to one of ordinary skill in the art to attach the transducer to the surgeon during use in order to ensure that the surgeon can hear the audible warning by blocking out ambient and background noise.

Claim 107 is rejected under 35 U.S.C. 103(a) as being unpatentable over SU733670 in view of Steinberg et al (US5746748). The claims differ from the previously cited prior art in calling for a sterile kit containing the device. Providing surgical cutting implements in sterile kit form is conventional and well known in the art as evidenced by Steinberg et al (US5746748) noting Figs. 9, 10 wherein a sterile kit houses the surgical implements so that a convenient, sterile, prepackaged unit was provided which precludes the need to prepare, clean, and resterilize the instruments prior to use. See col. 8, lines 43-62. In view of Steinberg et al (US5746748), it would have been obvious to one of ordinary skill in the art to provide a sterile kit including the device of the previously described apparatus so that a convenient, sterile, prepackaged

unit was provided which precludes the need to prepare, clean, and resterilize the instruments prior to use.

Response to Arguments

Applicant's arguments have been considered but are deemed to be moot in view of the new grounds of rejection. However, as noted in the rejection, the SU reference teaches detecting both static and dynamic forces. Specifically, the SU reference teaches that changes in the pressure exerted by the blade on the tissue is dynamically indicated by an associated proportional change in tone of the sound. Therefore, by monitoring such changes in pitch while cutting, the physician obtains real-time information regarding the changes in (1) tissue density, (2) tissue resistance, and (3) depth of the cut.

Final Rejection

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

Any inquiry concerning this or earlier communications from the examiner should be directed to John A. Jeffery at telephone number (703) 306-4601 or fax (703) 305-3463. The examiner can normally be reached on Monday-Thursday from 7:00 AM to 4:30 PM EST. The examiner can also be reached on alternate Fridays.

The fax phone numbers for the organization where this application or proceeding is assigned are:

Before Final	(703) 872-9302
After Final	(703) 872-9303
Customer Service	(703) 872-9301

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Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center receptionist whose telephone number is (703) 308-0861.

A handwritten signature in black ink, appearing to read "John A. Jeffery". The signature is fluid and cursive, with the first name "John" being the most prominent part.

**JOHN A. JEFFERY
PRIMARY EXAMINER**

12/2/02